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DOCKET NO.: 9511-087-27

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Re: Serial No.: 10/043,322
Applicant(s): Riichiro ABE, et al.
Filing Date: January 14, 2002
For: METHODS AND COMPOSITIONS FOR MODULATING
REGULATION OF THE CYTOTOXIC LYMPHOCYTE RESPONSE BY
MACROPHAGE MIGRATION INHIBITORY FACTOR
Group Art Unit: 1641
Examiner:

SIR:

Attached hereto for filing are the following papers:

INFORMATION DISCLOSURE STATEMENT
FORM PTO-1449
CITED DOCUMENTS (77)

Our check in the amount of \$ -0- is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary extension of time to make the filing of the attached documents timely, please charge or credit the difference to Deposit Account No. 50-1442. Further, if these papers are not considered timely filed, then a request is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

PIPER RUDNICK LLP

Steven B. Kelber
Attorney of Record
Registration No.: 30,073

Paul C. Kimball
Registration No. 34,641

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: Riichiro ABE, et al.

GROUP ART UNIT: 1641

SERIAL NUMBER: 10/043,322

EXAMINER:

FILED: January 14, 2002



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FOR: METHODS AND COMPOSITIONS FOR MODULATING REGULATION OF THE CYTOTOXIC LYMPHOCYTE RESPONSE BY MACROPHAGE MIGRATION INHIBITORY FACTOR

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

- Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents.

RELATED CASES

- ☐ Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:


- ☐ without fee and within three months of the filing date of the application.
- ☐ without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- ☐ without fee and with the appropriate certification above.
- ☐ without fee and with a new CPA application.
- ☐ without fee and with a Request for Continued Examination.
- ☐ with fee and before the mailing date of any of a Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
- ☐ with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

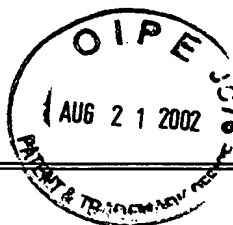
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LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)				APPLICANT			
				Riichiro ABE, et al.			
				FILING DATE		GROUP ART UNIT	
				January 14, 2002		1641	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4,946,778	8/7/90	Ladner, et al.			
	AB	6,030,615	2/29/00	Bucala, et al.			
	AC	6,080,407	6/27/00	Bucala, et al.			
	AD						
FOREIGN PATENT DOCUMENTS							
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					YES NO		
	AE						
	AF						
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AG	Köhler, et al., "Continuous Cultures of Fused Cells Secreting Antibody of Predetermined Specificity", Nature, 256, 495-497 (1975).					
	AH	Kozbor, et al., "The Production of Monoclonal Antibodies from Human Lymphocytes", Immunology Today, 4, 3, 72-79 (1983).					
	AI	Cote, et al., "Generation of Human Monoclonal Antibodies Reactive with Cellular Antigens", Proc. Natl. Acad. Sci., 80, 2026-2030 (1983).					
	AJ	Cole, et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer", Monoclonal Antibodies and Cancer Therapy, Alan R. Liss, Inc., 77-96 (1985).					
	AK	Morrison, et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains", Proc. Natl. Acad. Sci., 81, 6851-6855 (1984).					
	AL	Neuberger, et al., "Recombinant Antibodies Possessing Novel Effector Functions", Nature, 312, 13, 604-608 (1984).					
	AM	Takeda, et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences", Nature, 314, 4, 452-454 (1985).					

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LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		APPLICANT Riichiro ABE, et al.		FILING DATE January 14, 2002		GROUP ART UNIT 1641	
AN	Huse, et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", Science, 246, 1275-1281 (1989).						
AO	Metz, et al., "Role of Macrophage Migration Inhibitory Factor in the Regulation of the Immune Response" Adv.Immunol., 66, 197-223 (1997).						
AP	Bloom, et al., "Mechanisms of a Reaction in Vitro Associated with Delayed-Type Hypersensitivity", Science, 153, 80-82. (1966).						
AQ	David, "Delayed Hypersensitivity In Vitro: Its Mediation by Cell-Free Substances Formed by Lymphoid-Antigen Interaction", Proc. Natl. Acad. Sci. U.S.A., 56, 72-77 (1966).						
AR	Bernhagen, et al., "MIF is a Pituitary-Derived Cytokine that Potentiates Lethal Endotoxaemia", Nature, 365, 756-759 (1993) [published erratum appears in Nature 1995 Nov 23, 378(6555),419].						
AS	Calandra, et al., "The Macrophage is an Important and Previously Unrecognized Source of Macrophage Migration Inhibitory Factor", J. Exp. Med., 179, 1895-1902 (1994).						
AT	Calandra, et al., "Macrophage Migration Inhibitory Factor is a Critical Mediator of the Activation of Immune Cells by Exotoxins of Gram-Positive Bacteria", Proc. Nat'l. Acad. Sci. U.S.A., 95, 11383-11388 (1998).						
AU	Calandra, et al., "Protection from Septic Shock by Neutralization of Macrophage Migration Inhibitory Factor", Nat. Med., 6, 2, 164-170 (2000).						
AV	Bacher, et al., "An Essential Regulatory Role for Macrophage Migration Inhibitory Factor in T-Cell Activation", Proc. Natl. Acad. Sci. USA., 93, 7849-7854 (1996).						
AW	Chesney, et al., "An Essential Role for Macrophage Migration Inhibitory Factor (MIF) in Angiogenesis and the Growth of a Murine Lymphoma", Mol. Med., 5, 181-191 (1999).						
AX	Shimizu, et al., "High Expression of Macrophage Migration Inhibitory Factor in Human Melanoma Cells and Its Role in Tumor Cell Growth and Angiogenesis", Biochem. and Biophys. Res. Commun., 264, 751-758 (1999).						
AY	Moore, et al., "Introduction of Soluble Protein into the Class I Pathway of Antigen Processing and Presentation", Cell, 54, 777-785 (1988).						
AZ	Bendrat, et al., "Biochemical and Mutational Investigations of the Enzymatic Activity of Macrophage Migration Inhibitory Factor", Biochemistry, 36, 15356-15362 (1997).						

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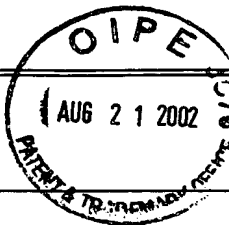
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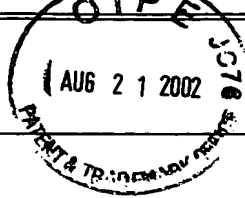
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BA	Bernhagen, et al., "Purification, Bioactivity, and Secondary Structure Analysis of Mouse and Human Macrophage Migration Inhibitory Factor (MIF)", Biochemistry, 33, 14144-14155 (1994).
BB	Calandra, et al., "MIF as a Glucocorticoid-Induced Modulator of Cytokine Production", Nature, 377, 68-71 (1995).
BC	Ke, et al., "Ovalbumin Injected with Complete Freund's Adjuvant Stimulates Cytolytic Responses", Eur. J. Immunol., 25, 549-553 (1995).
BD	Hashimoto, et al., "Differential Antitumor Effects of Administration of Recombinant IL-18 or Recombinant IL-12 Are Mediated Primarily by Fas-Fas Ligand- and Perforin-Induced Tumor Apoptosis, Respectively", J. Immunol., 163, 583-589 (1999).
BE	Taetle, et al., "Use of Nude Mouse Xenografts as Preclinical Drug Screens: In Vivo Activity of Established Chemotherapeutic Agents Against Melanoma and Ovarian Carcinoma Xenografts", Cancer Treat. Rep., 71, 3, 297-304 (1987).
BF	Zou, et al., "Tumor-Bearing Mice Exhibit a Progressive Increase in Tumor Antigen-Presenting Cell Function and a Reciprocal Decrease in Tumor Antigen-Responsive CD4 ⁺ T Cell Activity", J. Immunol., 148, 2, 648-655 (1992).
BG	Rosenblatt-Velin, et al., "Transformed and Nontransformed Human T Lymphocytes Migrate to Skin in a Chimeric Human Skin/SCID Mouse Model", J. Invest. Dermatol., 109, 6, 744-750 (1997).
BH	Bernhagen, et al., "An Essential Role for Macrophage Migration Inhibitory Factor in the Tuberculin Delayed-Type Hypersensitivity Reaction", J. Exp. Med., 183, 277-282 (1996).
BI	Berke, G. et al., "The CTL's Kiss of Death", Cell, 81, 9-12 (1995).
BJ	Apte, et al., "Cutting Edge: Role of Macrophage Migration Inhibitory Factor in Inhibiting NK Cell Activity and Preserving Immune Privilege" J. Immunol., 160, 5693-5696 (1998).
BK	Nelson, et al., "Biology of the Interleukin-2 Receptor", Adv. Immunol., 70, 1-81 (1998).
BL	Nelson, et al., "A Membrane-Proximal Region of the Interleukin-2 Receptor γ Chain Sufficient for Jak Kinase Activation and Induction of Proliferation in T Cells", Mol. Cell Biol., 16, 1, 309-317 (1996).
BM	Nelson, et al., "Cytoplasmic Domains of the Interleukin-2 Receptor β and γ Chains Mediate the Signal for T-cell Proliferation", Nature, 369, 333-336 (1994).

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	BN	Dai, et al., "The Role of the Common Cytokine Receptor γ -Chain in Regulating IL-2-Dependent, Activation-Induced CD8 ⁺ T Cell Death", J. Immunol., 163, 3131-3137 (1999).					
	BO	Jäger, et al., "CTL-Defined Cancer Vaccines: Perspectives for Active Immunotherapeutic Interventions in Minimal Residual Disease", Cancer and Metastasis Rev., 18, 143-150 (1999).					
	BP	Dunbar, et al., "Cutting Edge: Rapid Cloning of Tumor-Specific CTL Suitable for Adoptive Immunotherapy of Melanoma", J. Immunol., 162, 6959-6962 (1999).					
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	BR	Yamasaki, et al., "Immunoregulatory Effects of Interleukin 2 and Interferon on Syngeneic Murine Malignant Glioma-Specific Cytotoxic T-Lymphocytes", Cancer Res., 48, 2981-2987 (1988).					
	BS	Renauld, et al., "Accessory Signals In Murine Cytolytic T Cell Responses Dual Requirement for IL-1 and IL-6", J. Immunol., 143, 6, 1894-1898 (1989).					
	BT	Smyth, et al., "IL-2 and IL-6 Synergize to Augment the Pore-Forming Protein Gene Expression and Cytotoxic Potential of Human Peripheral Blood T Cells", J. Immunol., 145, 4, 1159-1166 (1990).					
	BU	Kasper, et al., "IL-7 Stimulates Protective Immunity in Mice Against the Intracellular Pathogen, Toxoplasma gondii", J. Immunol., 155, 4798-4804 (1995).					
	BV	Chen, et al., "IL-10: A Novel Cytotoxic T Cell Differentiation Factor", J. Immunol., 147, 2, 528-534 (1991).					
	BW	Gately, et al., "Administration of Recombinant IL-12 to Normal Mice Enhances Cytolytic Lymphocyte Activity and Induces Production of IFN- γ in vivo", Int. Immunol., 6, 1, 157-167 (1994).					
	BX	Gately, et al., "Regulation of Human Cytolytic Lymphocyte Responses by Interleukin-12", Cell. Immunol., 143, 127-142 (1992).					
	BY	Mehrotra, et al., "Effects of IL-12 on the Generation of Cytotoxic Activity in Human CD8 ⁺ T Lymphocytes", J. Immunol., 151, 5, 2444-2452 (1993).					
	BZ	Ciolli, et al., "Combined Interleukin 1/Interleukin 2 Therapy of Mice Injected with Highly Metastatic Friend Leukemia Cells: Host Antitumor Mechanisms and Marked Effects on Established Metastases", J. Exp. Med., 173, 313-322 (1991).					

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CA	Rosenberg, et al., "Regression of Established Pulmonary Metastases and Subcutaneous Tumor Mediated by the Systemic Administration of High-Dose Recombinant Interleukin 2", J. Exp. Med., 161, 1169-1188 (1985).					
CB	Nastala, et al., "Recombinant IL-12 Administration Induces Tumor Regression in Association with IFN- γ Production", J. Immunol., 153, 1697 (1994).					
CC	Hashimoto, et al., "Cytotoxic NK1.1 Ag $^+$ $\alpha\beta$ T Cells with Intermediate TCR Induced in the Liver of Mice by IL-12", J. Immunol., 154, 4333-4340 (1995).					
CD	Brunda, et al., "Interleukin-12: Murine Models of a Potent Antitumor Agent", Ann. N.Y. Acad. Sci., 795, 266-274 (1996).					
CE	Brunda, et al., "The Anti-Tumor Effect of Recombinant Interferon Alpha or Gamma is Influenced by Tumor Location", Int. J. Cancer, 40, 807-810 (1987).					
CF	Sayers, et al., "Antitumor Effects of α -Interferon and γ -Interferon on a Murine Renal Cancer (Renca) in Vitro and in Vivo", Cancer Res., 50, 5414-5420 (1990).					
CG	Giovarelli, et al., "Interferon-Activated Tumor Inhibition <i>in vivo</i> . Small Amounts of Interferon-Gamma Inhibit Tumor Growth by Eliciting Host Systemic Immunoreactivity", Int. J. Cancer, 37, 141-148 (1986).					
CH	Mulé, et al., "Antitumor Effect of Recombinant Tumor Necrosis Factor- α Against Murine Sarcomas at Visceral Sites: Tumor Size Influences the Response to Therapy", Cancer Immunol. Immunother., 26, 202-208 (1988).					
CI	Good, et al., "IL-2 and IL-4 Can Co-Modulate the Generation of Cytotoxic T Cells Through CD8 $^+$ CD4 $^+$ Splenic Lymphocytes", Immunology, 67, 225-230 (1989).					
CJ	Yamashita, et al., "Suppressive Activity of Interleukin 4 on the Induction of Antigen-Specific Cytotoxic T Cells in Humans", Jpn. J. Cancer Res., 82, 585-592 (1991).					
CK	Jin, et al., "TGF β Down-Regulates TLIS1 Expression and Inhibits the Differentiation of Precursor Lymphocytes into CTL and LAK cells", Immunology 66, 570-576 (1989).					
CL	Erard, et al., "Switch of CD8 T Cells to Noncytolytic CD8 $^+$ CD4 $^+$ Cells that Make T $_H$ 2 Cytokines and Help B Cells", Science, 260, 1802-1805 (1993).					
CM	Croft, et al., "Generation of Polarized Antigen-Specific CD8 Effector Populations: Reciprocal Action of Interleukin (IL)-4 and IL-12 in Promoting Type 2 Versus Type 1 Cytokine Profiles", J. Exp. Med., 180, 1715-1728 (1994).					

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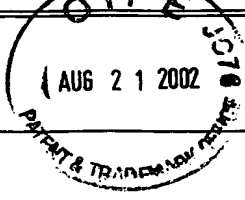
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	CN	Noble, et al., "IFN- γ and IL-4 Regulate the Growth and Differentiation of CD8 ⁺ T Cells into Subpopulations with Distinct Cytokine Profiles", J. Immunol., 155, 2928-2937 (1995).					
	CO	Takahashi, et al., "Involvement of Macrophage Migration Inhibitory Factor (MIF) in the Mechanism of Tumor Cell Growth", Mol. Med., 4, 707-714 (1998).					
	CP	Meyer-Siegler, et al., "Enhanced Expression of Macrophage Migration Inhibitory Factor in Prostatic Adenocarcinoma Metastases", Urology, 48, 3, 448-452 (1996).					
	CQ	Rees, et al., "Selective MHC Expression in Tumours Modulates Adaptive and Innate Antitumour Responses", Cancer Immunol. Immunother., 48, 374-381 (1999).					
	CR	Hahne, et al., "Melanoma Cell Expression of Fas(Apo-1/CD95) Ligand: Implications for Tumor Immune Escape", Science, 274, 1363-1366 (1996).					
	CS	Strand, et al., "Lymphocyte Apoptosis Induced by CD95 (APO-I/Fas) Ligand-Expressing Tumor Cells--A Mechanism of Immune Evasion?", Nat. Med., 2, 12, 1361-1366 (1996).					
	CT	Arai, et al., "Gene Transfer of Fas Ligand Induces Tumor Regression in vivo", Proc. Nat'l. Acad. Sci. U.S.A., 94, 13862-13867 (1997).					
	CU	Kang, et al., "Fas Ligand Expression on Islets as Well as Multiple Cell Lines Results in Accelerated Neutrophilic Rejection", Transplant. Proc., 30, 538 (1998).					
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	CX	Allison, et al., "Transgenic Expression of CD95 Ligand on Islet β Cells Induces a Granulocytic Infiltration but Does Not Confer Immune Privilege upon Islet Allografts", Proc. Nat'l. Acad. Sci. U.S.A., 94, 3943-3947 (1997).					
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	CZ	Straten, et al., "In situ T cells in Melanoma", Cancer Immunol. Immunother., 34, 386-395 (1999).					

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		DA	Hudson, et al., "A Proinflammatory Cytokine Inhibits p53 Tumor Suppressor Activity", J. Exp. Med., 190, 10, 1375-1382 (1999).			
DB	Matsumura, et al., "Emerging Principles for the Recognition of Peptide Antigens by MHC Class I Molecules", Science, 257, 927-934 (1992).					
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